In the Supreme Court of the United States

OCTOBER TERM, 1972

No. 72-528

CIBA CORPORATION, PETITIONER

v.

ELLIOT L. RICHARDSON, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND DR. CHARLES C. EDWARDS, COMMISSIONER OF FOOD AND DRUGS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MEMORANDUM FOR THE RESPONDENTS

1. Petitioner manufactures a drug product, Ritonic Capsules, for which it filed a New Drug Application (NDA) that became effective in 1958. Subsequent to the passage of the 1962 amendments to the Federal Food, Drug, and Cosmetic Act of 1938, which authorized the Food and Drug Administration (FDA) to withdraw approval of the NDAs of certain drugs if the manufacturer could not establish their effectiveness, FDA commenced proceedings to withdraw approval of Ritonic Capsules' NDA. These proceedings culminated in a withdrawal of the NDA, and Ciba petitioned for review of that action, under Section

489-351—72

505(h) of the Act, to the Court of Appeals for the Second Circuit, which affirmed the action of FDA. *Ciba-Geigy Corp.* v. *Richardson*, 446 F. 2d 466. Supreme Court review of that decision was not sought. Petitioner also filed the present declaratory judgment action in the District Court for the District of New Jersey, seeking a declaration that its product was not a "new drug" and could therefore be freely marketed notwithstanding the withdrawal of the NDA. The district court declined, in its discretion, to entertain the action, and the court of appeals affirmed (Pet. App. 9a–10a).

2. In the declaratory judgment action, petitioner contended that its drug was marketable under two theories: (1) that it was exempt from the efficacy requirements of the 1962 amendments under the terms of the grandfather clause contained therein (P.L. 87-781, Section 107(c)(4), 76 Stat. 789, note following 21 U.S.C. 321 (1970 ed.)) because it had come to be generally recognized as safe by 1962; (2) that it does not now fall within the statutory definition of a "new drug" requiring an approved NDA because it is presently generally recognized as safe and effective.[1] On appeal, petitioner presented the question whether the district court had jurisdiction to entertain the

[1] Section 201(p) of the Act defines a "new drug" (for purposes material here) as: "Any drug * * * the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof * * *." 21 U.S.C. 321(p)(1).

declaratory judgment action and whether dismissal of the action was a proper exercise of the court's discretion. In support of its appeal petitioner urged, as it does in this Court, that FDA is without jurisdiction to determine the questions presented in the declaratory judgment proceeding, and that they were therefore appropriately presented for resolution by the district court.

3. The court of appeals held that FDA had jurisdiction to decide the threshold question whether the product subject to NDA withdrawal proceedings is a "new drug" and that such a determination could have been reviewed in the direct judicial review proceedings in the Second Circuit. Since the court was of the view that petitioner's contentions should have been raised before the agency and on direct judicial review, it concluded, without expressly reaching the issue of the district court's jurisdiction to entertain the declaratory judgment action, that it "is neither necessary nor appropriate that the District Court for the District of New Jersey entertain a separate suit by the loser in the administrative proceeding and in the direct appeal therefrom for a redetermination of the same question" (Pet. App. 10a).

4. We believe that the court of appeals was correct in holding that petitioner should have submitted its contentions to FDA in the administrative proceedings and should not now be afforded the opportunity for fresh litigation of these issues in the district court. We agree with petitioner, however, that the decision of the court below on the scope of the FDA's authority is in conflict with the decision of the Fourth Cir-

cuit in *Bentex Pharmaceuticals, Inc.* v. *Richardson*, 463 F. 2d 363, from which the government has petitioned for a writ of certiorari, *Elliot Richardson, et al.* v. *Bentex Pharmaceuticals, Inc.*, No. 72-555.

Arguably, there is a distinction between the instant case and *Bentex*, since the latter involves drug products for which no NDA was ever effective, and therefore no NDA withdrawal proceedings were undertaken by the agency.[2] The reasoning of the Court of Appeals for the Fourth Circuit in *Bentex*, however, was based on the premise that FDA lacks jurisdiction to determine whether a drug product is subject to the Act, contrary to the conclusion of the court of appeals in the instant case. And in terms of the exercise of equitable discretion in deciding whether to entertain a declaratory judgment action, both cases raise the important question whether the agency or the courts should make the initial determination.[3]

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[2] Bentex and the other manufacturers joining as plaintiffs in the declaratory judgment action in the *Bentex* case manufactured drug products similar in formulation to a product for which another firm held an NDA. When the NDA was withdrawn, FDA took the position that the action covered the plaintiffs' products as well, and thus effectuated a withdrawal of their marketing authorization. This position was challenged in the declaratory judgment action, which presented the threshold question whether the factual and legal issues raised by, or the courts. The district court, in the exercise of its discretion, stayed the court proceedings in order to permit the agency to make the initial determination. The court of appeals held that only the courts had authority to determine these questions, and therefore reversed the decision of the district court.

[3] While the circuits are in conflict on the jurisdictional issue, it appears that the Court of Appeals for the Fourth Circuit, which would have reached the merits of petitioner's claims, would have ruled adversely to petitioner on the merits. See

the controversy should be initially determined by the agency

Because of the conflict between the circuits, and because the petition is one of several now pending that present related questions which are important to effective administration of the Food, Drug, and Cosmetic Act,[4] we do not oppose the granting of the petition for a writ of certiorari in this case.

Respectfully submitted.

ERWIN N. GRISWOLD,
Solicitor General.

PETER BARTON HUTT,
Assistant General Counsel,
Food, Drugs and Product Safety Division,
Department of Health, Education, and Welfare.

NOVEMBER 1972.

USV Pharmaceutical Corp. v. *Richardson*, 461 F. 2d 223, 226–228, *Westcott and Dunning, Inc.* v. *Richardson*, 461 F. 2d 215, 219, petitions for writs of certiorari pending, Nos. 72–394 and 72–414. The views of the Fourth Circuit on the merits, of course, do not eliminate the conflict on the jurisdictional issue.

[4] In addition to the government's petition in *Bentex*, and CIBA's petition in this case, there are also pending a petition by the government in *Richardson* v. *Hynson, Westcott & Dunning, Incorporated*, No. 72–394; a cross-petition in the same case, *Hynson Westcott & Dunning, Incorporated* v. *Richardson*, No. 72–414, which the government has urged the Court to grant; and a petition in *USV Pharmaceuticals Corp.* v. *Richardson*, No. 72–666.

petition for writ of certiorari pending, No. 72-666; Hynson,

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